No. 94-94-572

IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

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HELEN GILE,

Petitioner,

—v.—

OPTICAL RADIATION CORPORATION; XYZ COMPANIES #1 THROUGH #5, JOHN DOES #1 THROUGH #5,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

OPTICAL RADIATION CORPORATION'S BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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RULE 29.1 STATEMENT

Pursuant to Sup. Ct. R. 29.1, respondent Optical Radiation Corporation ("ORC") states that it has no parent company. While it has certain subsidiaries, all are wholly-owned.

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Respondent Optical Radiation Corporation ("ORC") respectfully requests that this Court deny the petition for writ of certiorari seeking review of the Third Circuit's decision in this matter.

STATEMENT OF THE CASE

Introduction

Petitioner's brief contains several misstatements of fact, along with other statements that, while perhaps not literally

inaccurate, could, as presented, create a misimpression. Pursuant to Sup. Ct. R. 15.1, respondent alerts the Court to such statements here. In so doing, respondent does not mean to imply that the misstatements bear in any way on the validity or correctness of the decision below. In fact, the Third Circuit's ruling is absolutely correct, and reaches the same result as that of every other Court of Appeal to have considered the identical issue raised here: preemption under 21 U.S.C. § 360k (see Point I below). Far from conflicting with *any* other Court of Appeal, the Third Circuit's opinion is entirely consistent with *every* other Court of Appeal that has addressed this issue.

The facts giving rise to this petition are significant, in one regard. The Third Circuit decided a narrow issue of law and applied a particular statute in the context of a specific case involving a particular plaintiff, a particular product, and the products liability law of a particular state. In each of these respects, this case is unique. The particular combination of facts and law makes the holding of the Third Circuit a narrow one, and likely of limited import to other litigants. Accordingly, wholly apart from the fact that the Third Circuit's interpretation of 21 U.S.C. § 360k was correct, and in accord with the decisions of this and other courts, *this* case is particularly ill-suited to serve as a vehicle for Supreme Court review of the applicable statute.

The Facts

Before undergoing surgery, petitioner Gile signed a lengthy informed consent document on November 15, 1985 (Resp't App. Ra1-Ra6.) (The informed consent document referenced in petitioner's brief, and set forth in Pet. App. 42a-49a, is dated March 15, 1985, and was for other eye surgery unrelated to this claim.) The informed consent document signed by petitioner explained, among other things, that:

> —she was being given the opportunity to participate in "an extensive clinical investigation of intraocular lenses to establish facts about the safety and efficacy of these lenses";
>
> —"your participation in this study is completely voluntary";
>
> —"the results of the cataract operation cannot be guaranteed in your or anyone's case";
>
> —"as a result of the surgery, it is possible that your vision could be made worse. * * * Complications may include hemorrhage (bleeding), loss of corneal clarity, infection, detachment of the retina, glaucoma, and/or double vision";
>
> —"insertion of an intraocular lens may induce complications which otherwise would not occur. * * * Complications may include a loss of corneal clarity, infection, uveitis, iris atrophy, glaucoma, bleeding in the eye, inability to dilate the pupil, dislocation of the lens and retinal detachment";
>
> —"at some future time, the lens implanted in your eye may have to be repositioned or removed surgically."

In signing the informed consent, petitioner acknowledged:

> I understand that the implanting of this intraocular lens in my eye is part of a clinical investigation and that periodic visits to the doctor by me will be required for at least one year to evaluate the results of my operation.

On November 26, *1986* (not 1985, as set forth in petitioner's brief), respondent suspended the clinical investigation that had been ongoing for some five years. Petitioner's statements about the number of patients with implanted lenses are without foundation in the record. Respondent disputes the various figures set forth in petitioner's brief, and specifically disputes the claim that approximately one percent (500 of over 57,000 patients) suffered any injury *as a result of* the use

of this type of intraocular lens. (Some percentage of patients undergoing any surgical procedure will, of course, experience a complication of the procedure itself.)

Of greater significance, respondent specifically denies that there are hundreds, thousands, or any other large number of pending lawsuits against it arising out of this clinical investigation. While there have been lawsuits filed against the respondent over the years, virtually all of them have been adjudicated, settled, or otherwise disposed of. Currently, there are only some ten such active cases. To the extent petitioner hints that the Third Circuit's decision—or any review by this Court—will affect large masses of litigants, that suggestion is simply wrong.

REASONS FOR DENYING THE WRIT

Summary of Argument

In the last two years, this Court has thrice declined to review decisions virtually identical to that of the Third Circuit, upholding the preemptive effect of 21 U.S.C. § 360k. One of those cases involved the same investigational lens at issue here. *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992), *cert. denied*, 113 S. Ct. 327 (1992) (intraocular lens); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir. 1993), *cert. denied*, 114 S. Ct. 84 (1993), *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), *cert. denied*, 114 S. Ct. 86 (1993). This case is particularly inappropriate for Supreme Court review. This petition, too, should be denied.

Far from being in conflict with any other Court of Appeal, the Third Circuit's opinion is in harmony with every other circuit court to have addressed this issue. In addition to the First, Fifth and Seventh Circuits, the Eleventh Circuit, in the context of investigational intraocular lens cases, has upheld preemption under 21 U.S.C. § 360k. *Duncan v. IOLAB Corp.*, 12 F.3d 194 (11th Cir. 1994); *Hinners v. Optical Radiation Corp.*, 15 F.3d 1096 (11th Cir. 1994). The Third Circuit's

opinion is not a novel or unusual ruling; rather, it is in the mainstream of judicial thinking on this issue.

Nor is there anything special or peculiar about the facts of this case to warrant Supreme Court review. Indeed, these facts—because they limit the scope of the decision below—militate against further review. The thrust of petitioner's complaint is that, notwithstanding the clear terms of the informed consent document she signed, she was somehow inadequately informed about the investigational nature of this lens. However, as the Third Circuit pointed out, under applicable state law (New Jersey's), the duty to obtain informed consent rests with the surgeon, not the device manufacturer. *Gile v. Optical Radiation Corporation*, 22 F.3d 540, 543 (3d Cir. 1994). (Pet. App. 9a.) Of significance to this petition is the fact that, according to the Third Circuit:

> . . . Gile is not precluded from asserting a right of redress in the state forum because her claims against her physician are not preempted under the MDA. . . . Gile is not left without a remedy because she may still pursue her claims, if any, against her physician in state court.

22 F.3d at 546.[1] (Pet. App. 16a.) If petitioner proceeds under the claim expressly left available to her by the Third Circuit, then this petition could well become moot.

This petition raises no significant constitutional issues. The Third Circuit's interpretation of 21 U.S.C. § 360k is in accord with that of every other Court of Appeal to have considered the issue. In all events, the holding below was a narrow one, of limited impact beyond this one case. Because petitioner may yet have a remedy against other parties, this entire issue may ultimately be irrelevant. The petition should be denied.

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[1] In that regard, it is important to note that petitioner's original Complaint apparently preserved causes of action against "John Doe" defendants, as permitted under New Jersey law. Pressler, Current N.J. Ct. R. 4:26-4.

I. There Is No Conflict Among The Circuits

The Medical Device Amendments (MDA) contain an express preemption provision, 21 U.S.C. § 360k. The preemptive scope of 21 U.S.C. § 360k is articulated not only in the express language of the statute, but also in the reasoned opinions of the circuit courts. Commencing with *Slater*, 961 F.2d 1330, the First, Fifth, Seventh and Eleventh Circuits have considered the preemptive effect of 21 U.S.C. § 360k(a), concluding—in every case—that tort and other claims such as those advanced in this case are "requirements" expressly preempted by the statute. *Duncan*, 12 F.3d 194; *Stamps*, 984 F.2d 1416; *King*, 983 F.2d 1130; *see also Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744 (M.D. Pa. 1992), *aff'd*, 5 F.3d 1489 (3d. Cir. 1993).

The Third Circuit did not blaze a new trail of statutory interpretation or embrace a novel or idiosyncratic reading of 21 U.S.C. § 360k when it affirmed the district court's decision. Instead, it followed a well-beaten path: all circuit courts that have considered the preemptive effect of 21 U.S.C. § 360k have concluded that common law tort and related claims are expressly preempted. On this score, the Courts of Appeal are in complete accord.

This Court has long observed that the writ of certiorari may be granted "in cases where there is a real and embarrassing conflict of opinion and authority between the circuit courts of appeal." *See Powell v. Nevada*, 114 S. Ct. 1280, 1284 (1994) (Thomas, J. dissenting) (quoting *Layne & Bowler Corp. v. Western Well Works, Inc.*, 261 U.S. 387, 393 (1923)). Here, there is no such conflict.

II. Petitioner Has Other, Unexplored Remedies That, If Pursued, Could Render This Claim Moot

Petitioner suggests that the opinion below deprives her of any opportunity to receive compensation for her claimed injuries. In fact, the Third Circuit's opinion is clearly to the contrary.

Distilled to its essence, petitioner's claim revolves around the alleged inadequacy of the information she was given regarding this investigational lens. Yet, under New Jersey law—the state law applicable to this tort claim—personal injury claims against product makers are carefully circumscribed. *See* N.J.S.A. 2A:58C-1-5. Claims of lack of "informed consent" do not lie against a product manufacturer, but against physicians and other health care providers. *See Gile*, 22 F.3d at 543 (and cases cited therein). (Pet. App. 9a-10a.)

The Third Circuit was clear in its holding: claims by petitioner against her physician, for inadequacies in the informed consent process, are not preempted. If petitioner pursues those claims, she can receive full compensation. Yet, to this point, petitioner apparently has chosen not to do so.

The fact that other remedies may yet be available to petitioner further suggests that this Court should not expend its resources on this matter.

III. Petitioner's State Law Claims Are "Requirements" Preempted By 21 U.S.C. § 360k

Petitioner argues here, as she did below, that the term "requirement," as used in 21 U.S.C. § 360k, cannot encompass state tort and related claims. On that issue of statutory interpretation, this Court's decision in *Cipollone v. Liggett Group*, 112 S. Ct. 2608 (1992) is instructive and, respondent submits, dispositive. In *Cipollone*, this Court interpreted the preemption provisions in the Federal Cigarette Labeling and Advertising Act ("the 1965 Act") and in the Public Health Cigarette Smoking Act of 1969 ("the 1969 Act"). The 1969 Act replaced the preemption provision contained in the 1965 Act with the following language:

> *No requirement or prohibition* based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the pack-

> ages of which are labeled in conformity with the provisions of this Act.

112 S. Ct. at 2617 (emphasis added). The 1969 Act is similar to 21 U.S.C. § 360k(a), insofar as both statutes employ the term "requirement" in defining the breadth of preemption.

Neither the 1965 Act nor the 1969 Act (nor the MDA) contains any reference to "tort law" or "common law" or "personal injury actions." Nevertheless, this Court concluded that the words "requirement or prohibition" in the 1969 Act expressed Congress's clear intent to preempt not only positive legislative enactments, but also common law claims for damages. 112 S. Ct. at 2620. In so doing, this Court held:

> The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."

112 S. Ct. at 2620 (quoting *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)).

In interpreting and applying 21 U.S.C. § 360k, the circuit courts, guided in part by *Cipollone*, have found that the word "requirement" in 21 U.S.C. § 360k refers to tort and related claims. *See Stamps*, 984 F.2d at 1421; *King*, 983 F.2d at 1133-34.

Casting aside the reasoning employed by this Court in *Cipollone*, and that employed by the various circuits, petitioner argued below, as she does here, that the word "requirement" is ambiguous and refers only to positive legislative enactments, not common law claims. *Gile*, 22 F.3d at 542.

(Pet. App. 7a.) Relying upon *Cipollone*, *Slater*, *Stamps*, and *King*, the Third Circuit unequivocally rejected petitioner's argument:

> [T]he Supreme Court has clearly stated that the word "requirement," in the context of an express preemption provision, includes state law claims.
>
> [Plaintiff] contends that there cannot be express preemption unless Congress uses "the words 'common law' or something analogous" to indicate its intent to preempt such claims. However, the MDA, providing "no State or political subdivision of a State may establish . . . any requirement . . . different from, or in addition to, any requirement applicable under this chapter," is indistinguishable from the act at issue in *Cipollone*, which provided, "[n]o requirement or prohibition . . . shall be imposed under State law with respect to the advertising . . . of any cigarettes." Thus, [plaintiff's] argument that Congress needs to explicitly provide that common law claims are preempted in order to find express preemption is unpersuasive.

22 F.3d at 542-43 (citations omitted). (Pet. App. 8a.)

The reasoning of the Third Circuit is sound, as the teaching of *Cipollone* is clear: in the context of an express preemption provision, the word "requirement" includes state law claims. Since *Cipollone*, the federal circuit courts have consistently found that the word "requirement" in 21 U.S.C. § 360k refers to tort and related personal injury claims. These holding are buttressed by the regulations implementing 21 U.S.C. § 360k. *See* 21 C.F.R. § 808.1(b).

In rhetoric unfettered by citation to any case law, petitioner claims that the five circuit courts to have considered 21 U.S.C. § 360k, including the court below, have all "misinterpreted the language of the MDA."[2] (Pet. at 8.) Without case

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[2] The only case cited in Point I of Petitioner's Brief that purportedly supports her argument is *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D.Md. 1989). In fact, this case provides no support for

law to support her crabbed interpretation of 21 U.S.C. § 360k, petitioner directs the Court to scattered sections of the MDA, including 21 U.S.C. §§ 360h(d), 360pp(e), 360pp(f) and 360g(e). These provide no refuge for petitioner.

Section 360h(d), which states that compliance with certain orders of the Secretary of Health and Human Services "shall not relieve any person from liability under Federal or State law," does not support petitioner's claim that state common law claims are not preempted. That view is expressed nowhere in the text of 21 U.S.C. § 360h, and finds no support in the case law. Moreover, a more logical and plausible reading of 21 U.S.C. § 360h(d) is that compliance with an order from the Secretary pursuant to 21 U.S.C. § 360h does not necessarily relieve a device manufacturer from other enforcement actions, such as seizures, or other criminal or civil actions, that may be pursued by the FDA, the Department of Justice, or other agencies. Such an interpretation permits 21 U.S.C. § 360h to be harmonized with 21 U.S.C. § 360k. *Cf. Hunsaker*, 818 F. Supp. 744.

Section 360pp is wholly inapplicable to this case. That section concerns enforcement of statutorily prescribed standards for electronic products. Plainly, that section and related sections—21 U.S.C. §§ 360oo and 360kk—have nothing whatsoever to do with intraocular lenses. More significantly, 21 U.S.C. § 360pp sets forth civil penalties that may be obtained *by the government* for violation of the relevant statutes. 21 U.S.C. § 360pp(b). No private right of action is created, nor can any be implied. *E.g.*, *National Women's Health Network v. A.H. Robins Co.*, 545 F. Supp. 1177 (D. Mass. 1982).

Section 360g is also irrelevant. That section concerns venue and related requirements imposed on manufacturers seeking judicial review of regulations affecting various types of med-

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petitioner's position. First, the case pre-dates *Cipollone*. Second, and perhaps most significantly, the case concerns an IUD, which is classified by the Food and Drug Administration (FDA) as a drug, not a medical device; accordingly, the MDA was inapplicable and therefore irrelevant to the case's holding. 709 F.Supp. at 666.

ical devices. Section 360g(e), which purportedly supports petitioner's view, states only that persons aggrieved by such regulations may have remedies other than those specifically set forth in the statute. Section 360g has nothing whatsoever to do with personal injury actions, preemption, or any issue relevant to this petition.

In short, the Third Circuit found that the great weight of judicial authority, as well as Congressional intent, supports preemption here. The view that common law tort and related claims such as those advanced in this case are "requirements" expressly preempted by 21 U.S.C. § 360k has been uniformly embraced by every federal circuit court to have examined the issue. The strained interpretation of 21 U.S.C. § 360k offered by petitioner finds no support in the case law or the network of federal law governing intraocular lenses.

IV. The Plain Language Of 21 U.S.C. § 360k(a) Supports Preemption And Is Consistent With Congressional Intent

Under petitioner's view, there can never be preemption unless Congress actually uses words to the effect that "common law claims are preempted." This argument is contrary to *Cipollone*'s teaching, is inconsistent with Congress' actions in respect of other legislation, and is at variance with the complete legislative history of the MDA.

A. When Congress wishes to preserve state law claims from preemption, it knows how to do so

Congress has repeatedly demonstrated its ability to include "savings clauses" or other language in statutes to express its intention that preemption *not* apply. In the Consumer Product Safety Act, 15. U.S.C. §§ 2051-2084—an act on which petitioner relies to support *her* argument—Congress provided a savings clause in 15 U.S.C. § 2074(a). (*See* Pet. at 15.) Similarly, in the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. §§ 4401-4408, Congress provided:

> Nothing in this chapter shall relieve any person from liability at common law or under State statutory law to any other person.

15 U.S.C. § 4406(c). *See also Cipollone v. Liggett Group*, 593 F. Supp. 1146, 1154 (D.N.J. 1984) (noting existence of 50 examples of such "savings clauses"). When Congress intends that preemption *not* apply, it knows how to do so, by including a savings clause. There is no such clause in the MDA.

B. Enactment of the 1990 and 1992 Amendments to the Medical Device Amendments of 1976 supports preemption and the Third Circuit's interpretation of 21 U.S.C. § 360k

Petitioner argues that because Congress made no changes to 21 U.S.C. § 360k when it amended the MDA in 1990, it must have assumed that preemption would not apply, since "[i]n 1990, the prevailing law was that section 360k did not expressly preempt common law." (Pet. at 14.) This assertion is incorrect. By 1990, a number of courts—primarily in the context of tampon litigation—had found that 21 U.S.C. § 360k(a) expressly preempted certain common law claims. *See, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989), *reh'g denied, en banc*, 873 F.2d 297 (5th Cir. 1989) (finding state law-based failure to warn and labeling claims preempted by 360k); *LaVetter v. International Playtex*, 706 F. Supp. 722 (D. Ariz. 1988); *Edmondson v. International Playtex, Inc.*, 678 F. Supp. 1571 (N.D. Ga. 1987). This list is not exhaustive; the cited cases cite, in turn, other supporting cases. Under petitioner's reasoning, by 1990 the "prevailing law" stated that 21 U.S.C. § 360k(a) *did* preempt certain state law claims—yet Congress did not take any steps to amend its legislation to change that rule of law.

More significantly (and not addressed in the petition) is the fact that in 1992 the Medical Device Amendments were *again* amended. Medical Device Amendments of 1992, P.L. 102-300, 106 Stat. 238. That legislation—which did not alter or amend 21 U.S.C. § 360k in any way—passed both houses of

Congress in May of 1992. By that time, the *Slater* opinions (in both the District Court and Seventh Circuit), upholding preemption under 21 U.S.C. § 360k, had been handed down. The "prevailing law" at the time of passage was that 21 U.S.C. § 360k preempted *all* common law claims, at least with respect to investigational intraocular lenses. Yet Congress took no action to indicate that those and the other preemption decisions in existence were contrary to its intent under 21 U.S.C. § 360k.

V. All Of Petitioner's Claims Against Optical Radiation Corporation Are Preempted

Petitioner argues that at least some of her claims are not preempted. Petitioner's arguments were considered and rejected below, as were similar arguments in the *King* and *Stamps* cases. These arguments do not support a grant of certiorari.

A. Petitioner has no "informed consent" claim against respondent

Petitioner relies on 21 C.F.R. § 50.25(c), dealing with the informed consent that must be given to participants in clinical trials of investigational devices, as support for her contention that her claim *against respondent* for failure to obtain informed consent is not preempted. (Pet. at 20-23.) This argument was addressed (and rejected) below. *Gile*, 22 F.3d at 543. (Pet. App. 8a-10a.)

First, under New Jersey law, a claim based on lack of informed consent—in reality, a claim for medical battery—does not lie against a product manufacturer. *See* N.J.S.A. 2A:58C-1 and 2. That claim lies against the physician—and that claim was expressly preserved by the Third Circuit. 22 F.3d at 546. (Pet. App. 16a.)

Second, the C.F.R. provisions dealing with informed consent can be applied without doing damage to the preemption provision contained in 21 U.S.C. § 360k. In *Hunsaker*, the

court examined the relationship between 21 U.S.C. § 360k and 21 C.F.R. § 50.20, and concluded that the two were complementary, not inconsistent. In rejecting essentially the same argument advanced by petitioner here, the court held:

> The consent regulation should be read to prevent patients from waiving legal rights which *are not preempted under federal law*. That is, those common law rights which are retained by a patient and not preempted by the federal scheme may not be waived by the patient.

818 F. Supp. at 750 (emphasis in original). The Third Circuit adopted this analysis in holding that while petitioner may have an "informed consent" claim against her physicians, she has no such claim against respondent. 22 F.3d at 543, 546. (Pet. App. 9a-10a, 16a.)

B. Petitioner has no implied warranty claims

Petitioner asserts claims for breaches of the implied warranties of fitness and merchantability, and argues that these are not preempted pursuant to 21 C.F.R. § 808.1(d)(1). (Pet. at 19-20.) As in the case of petitioner's informed consent arguments, the relevance and materiality of this issue to this particular case is lacking. The Uniform Commercial Code's implied warranties (codified in New Jersey at N.J.S.A. 12A:2-315 and 316) do not lie against product manufacturers. New Jersey's Product Liability Act did away with such claims. Implied warranty claims are no longer available to New Jersey plaintiffs alleging harm caused by a product. *See, e.g., Walus v. Pfizer, Inc.*, 812 F. Supp. 41, 43 (D.N.J. 1993) and cases cited therein.

As no implied warranty is available to plaintiff here, efforts to parse the meaning of 21 C.F.R. § 808.1(d)(1)'s reference to the U.C.C. are of limited significance. What is perhaps more significant is that 21 C.F.R. § 808.1(d)(1) is further evidence of FDA's ability to set forth discrete areas it views as *not* preempted under 21 U.S.C. § 360k. FDA is fully able to express its view on matters of preemption in its regulations—but it

has not done so in the case of tort and other common law claims.

C. Petitioner's "adulteration" argument is a red herring

Petitioner asserts that her claims cannot be preempted because the intraocular lens was "adulterated," and therefore exempt from preemption under 21 C.F.R. § 808.1(d)(6)(ii). (Pet. at 20.) This argument, too, was addressed and rejected below. 22 F.3d at 543-544. (Pet App. 10a-11a.)

As noted by the Third Circuit, petitioner's claim of "adulteration" was completely without foundation in the record. FDA made no findings of "adulteration." 22 F.3d at 544. (Pet. App. 11a.) Moreover, as the Third Circuit made clear, "to the extent [petitioner's] adulteration claim is derivative of her other claims for inadequate design, manufacture, and warnings, she cannot overcome a finding of preemption merely by claiming that the product was adulterated." 22 F.3d at 544. (Pet. App 11a.)

Finally, the Third Circuit specifically addressed petitioner's reliance on 21 C.F.R. § 808.1(d)(6)(ii). Pointing out that petitioner had failed to quote the regulation in its entirety, the Third Circuit found that the regulation *supported* preemption of petitioner's claims. 22 F.3d at 543-544. (Pet. App. 10a.) While 21 C.F.R. § 808.1(d)(6)(ii) generally does not present states from prohibiting the manufacture of adulterated devices, where such a prohibition has the effect of establishing a substantive requirement "different from, or in addition to" a federal requirement, it is preempted. In the words of the Third Circuit,

> This action by Gile challenging the design of the Stableflex lens and the warnings and instructions that accompanied it, if successful, would impermissibly result in new common law standards for lens designs and warnings. Thus, it is preempted.

22 F.3d at 543-544 (citations omitted). (Pet. App. 10a.)

D. Plaintiff's "fraud" claim is preempted

Petitioner also asserts, in passing, that her claim of fraudulent misrepresentation is also exempt from preemption. (Pet. at 23.) Petitioner never made any but the gauziest of allegations of "fraud." Despite the fact that discovery was extended at petitioner's request, she offered no proof of any such fraudulent misrepresentation.[3] Again, the FDA made no such findings of "fraudulent misrepresentation." If it had—and it did not—violations of the Food, Drug and Cosmetic Act and FDA regulations are punishable by significant fines, civil penalties, and imprisonment.

In reality, petitioner's claim of "fraudulent misrepresentations" is merely an alternate statement of her claim of inadequate warning and, accordingly is preempted as an impermissible attempt to impose safety requirements in addition to those mandated by FDA. Petitioner cannot elevate form over substance by presenting those warning claims under the heading "fraud." *See King*, 983 F.2d at 1136.

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[3] In that personal injury claims against product makers under New Jersey law are now circumscribed by statute, and in light of the fact that "fraudulent misrepresentation" is not recognized as an available cause of action, it is highly questionable whether petitioner even can state such a claim under applicable state law.

CONCLUSION

For these reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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Dated: August 30, 1994

APPENDIX

INFORMED CONSENT FOR CATARACT OPERATION AND/OR IMPLANTATION OF INTRAOCULAR LENS

INTRODUCTION

This information is given to you so that you can make an informed decision about having eye surgery. Take as much time as you wish to make your decision about signing this informed consent. You have the right to ask questions about any procedure before agreeing to have the operation.

Except for unusual problems, a cataract operation is indicated only when you cannot function adequately due to poor sight produced by the cataract. You must remember that the natural lens within your own eye with a slight cataract, although not perfect, has some distinct advantages over any man-made lens.

After your doctor has told you that you have a cataract, you and your doctor are the only ones who can determine if or when you should have a cataract operation—based on your own visual needs, and medical considerations, unless you have an unusual cataract that may need immediate surgery.

ALTERNATIVE TREATMENTS

You may decide not to have a cataract operation at all. However, should you decide to have an operation, you should understand completely the three methods of restoring useful vision after the operation. One (1) of the 3 methods listed below is required to correct your vision after surgery:

1. Spectacles (glasses)—Cataract spectacles are usually thicker and heavier than regular eyeglasses. Cataract spectacles increase the size of objects by about 25%. Clear vision is obtained only through the central part of cataract spectacles. This means you must learn to turn your head to see clearly on either side. Cataract spectacles usually cannot be used if a cataract is only in one eye (and the other is normal) because they may cause double vision.

2. Contact Lens—A hard or soft contact lens increases the size of objects only about 8%. Handling of a contact lens can be difficult for some individuals. Most lenses must be inserted and removed daily and not everyone can tolerate them. For near tasks, eyeglasses (not cataract spectacles) may be required in addition to contact lenses.

3. Intraocular Lens—This is a small plastic artificial lens with plastic supports which is surgically placed inside your eye permanently. The intraocular lens appears to show no change in the size of the objects you see. Conventional eyeglasses (not cataract spectacles) are usually needed in addition to an intraocular lens to give you the best vision possible.

Some intraocular lenses are investigational devices. Other intraocular lenses have been clinically proven as safe and effective. Your doctor can provide information to help you decide which intraocular lens is right for you, should you choose this method of restoring useful vision after the cataract operation.

CLINICAL INVESTIGATION

The United States Food and Drug Administration, in response to Congressional mandate, is requiring an extensive clinical investigation of intraocular lenses to establish facts about the safety and efficacy of these lenses. You have been asked to take part in this study because your doctor considers you a good candidate to help evaluate the intraocular lenses. The study involves a minimum one-year observation of the results of your surgery. The purpose of this observation is to compare in a similar group of patients the differences, if any, in eyes with and without lens implantations. Information about the results of your surgery will be made available to the Food and Drug Administration and to the lens manufacturer. The confidentiality of your medical records will be maintained by your doctor, the lens manufacturer, the hospital and the Food and Drug Administration, and your personal records will not be released or revealed beyond the scope of this study

without your permission. If for any reason you wish to decline participation in the study, you may do so without at all affecting your future medical care. It is estimated that over 500,000 individuals have received intraocular lenses as patients in this study. All questions pertinent to this investigation and concerning your rights as a study patient should be directed to you doctor.

CONSENT FOR OPERATION

In giving your permission for a cataract extraction and/or for the implantation of an intraocular lens in your eye, it is very important that you understand the following information:

1. Your participation in this study is completely voluntary. You will receive no compensation for participation in this study and you will suffer no penalty or loss of benefits as a result of study discontinuation. You may withdraw from the study at any time without consequence to your future medical care.

2. Cataract surgery, by itself, means the removal of the natural lens of the eye by a surgical technique. In order for an intraocular lens to be implanted in your eye, you must have cataract surgery performed either at the time of the lens implantation or before lens implantation.

3. If an intraocular lens is implanted, it is done by surgical method. It is intended that the small plastic lens with the plastic supports will remain in your eye permanently.

4. The results of the cataract operation cannot be guaranteed in your or anyone's case.

5. At the time of surgery, your doctor may decide not to implant an intraocular lens in your eye even though you may have given prior permission to do so.

6. *Complications of Surgery to Remove the Cataract*: As a result of the surgery, it is possible that your vision could be made worse. In some cases, complications may occur weeks, months or even years later. Complications may

include hemorrhage (bleeding), loss of corneal clarity, infection, detachment of the retina, glaucoma, and/or double vision. These and other complications may result in poor vision, total loss of vision or loss of the eye. These types of complications may occur whether or not an intraocular lens is implanted.

7. *Specific Complications of Lens Implantations*: Insertion of an intraocular lens may induce complications which otherwise would not occur. In some cases complications may develop during surgery from implanting the lens, or days, weeks, months or even years later. Complications may include loss of corneal clarity, infection, uveitis, iris atrophy, glaucoma, bleeding in the eye, inability to dilate the pupil, dislocation of the lens and retinal detachment.

8. At some future time, the lens implanted in your eye may have to be repositioned or removed surgically.

9. *Complications of Surgery in General*: As with all types of surgery, there is the possibility of other complications due to anesthesia, drug reactions or other factors which may involve other parts of your body, including a possibility of brain damage or even death. Since it is impossible to state every complication that may occur as a result of surgery, the list of complications in this form is incomplete. In the event of a study-related injury, you should contact your doctor immediately for medical care. IOLAB does not provide financial compensation and has no policy to provide medical or health care to any IOL recipient.

PATIENT STATEMENT

The basic procedures of cataract surgery and the advantages and disadvantages, risks and possible complications of alternative treatments have been explained to me by my doctor. Although it is impossible for my doctor to inform me of every possible complication that may occur, the doctor has answered all my questions to my satisfaction. I understand that the implanting of this intraocular lens in my eye is part of a clinical investigation and that periodic visits to the doctor

by me will be required for at least one year to evaluate the results of my operation. I give permission for medical data concerning my operation and subsequent treatment to be submitted to the lens manufacturer and to the FDA for the clinical study described. I understand I may withdraw from the clinical study at any time without jeopardizing my future medical care. In signing this Informed Consent for Cataract Operation and/or Implantation of Intraocular Lens, I am stating that I have read this informed consent (or it has been read to me). I fully understand the consent I am giving, and the possible risks, complications and benefits that can result from the surgery.

If I decide to have an operation, I agree to have the type of operation listed below which I have indicated by my signature:

(1) I wish to have a cataract operation without an intraocular lens implantation.

Patient's Signature_____

(2) I wish to have a cataract operation with an intraocular lens implantation.

Patient's Signature_____

(3) Since my cataract was previously removed and I have been informed by the doctor that my eye is medically acceptable for lens implantation, I wish to have an intraocular lens implanted.

Patient's Signature HELEN GILE

Patient's Name (Printed) HELEN GILE *Age* 66

Date 11/15/85 *Time* 3:00 p.m. *Place* RVEA

Witness' Signature MARTHA SCHROEDER

Doctor's Signature HENRY A. SCIMECA

INFORMATION FROM THE INTRAOCULAR LENS MANUFACTURER—IOLAB

The above information is the *minimum* information required by the United States Food and Drug Administration to be furnished to you for your consent for the operation and the extensive clinical investigation being made of intraocular lenses to determine facts about safety and efficacy.

Be informed—Your physician will furnish any additional information you require to be certain you are fully informed about the operation, the lens and the investigation.